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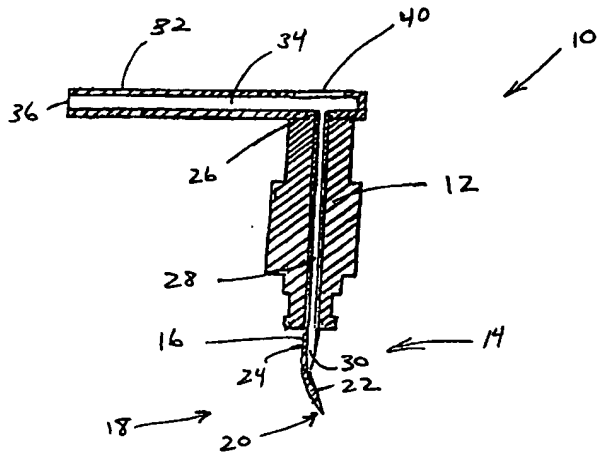
(54) Title: SAMPLING DEVICES AND METHODS FOR BODILY FLUIDS



(57) Abstract: Systems and methods for the sampling of bodily fluid from an incision in the skin include a sampling device (10) including an incising device (14) coupled with a housing (12). The incising device (14) includes a piercing portion (18) that extends outwardly of the housing (12) and includes a curved, angled or skewed portion. The housing (12) and/or the incising device (14) defines a sampling passageway (28) having an inlet opening (30) adjacent to, and on the interior side (22) of, the piercing portion (18). The piercing portion (18) protects the inlet opening (30) from becoming blocked or clogged by the body tissue, and facilitates the collection of the bodily fluid at the incision site. In another aspect, the present invention provides a test unit (60) that incorporates the sampling device (10) and is operable to incise the skin, collect the bodily fluid from the incision, and analyze a property or constituent of the bodily fluid. The present invention also encompasses methods for incising the skin and collecting the produced bodily fluid by use of a sampling device as described. In further embodiments, the invention includes the combination of the foregoing systems and methods with expressing and/or testing systems and methods, particularly in a single, integrated device.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Sampling Devices and Methods for Bodily Fluids

Reference to Related Applications/Patents

This application is related to and claims priority from provisional US Patent Applications, Serial Nos. 60/297,098 filed on June 8, 2001 (1123P), and 60/324,514 filed on September 26, 2001 (1127P). The disclosures in the foregoing applications are hereby incorporated by reference.

Background of the Invention

Field of the Invention

The present invention relates to the sampling of a bodily fluid obtained from an incision in the skin, and more particularly to devices and methods utilizing curved, angled or skewed incising devices to facilitate the collection of the bodily fluid. The invention also includes the combination of such devices and methods with expressing and/or testing systems.

Description of the Prior Art

The acquisition and testing of bodily fluids is useful for many purposes, and continues to grow in importance for use in medical diagnosis and treatment, and in other diverse applications. In the medical field, it is desirable for lay operators to perform tests routinely, quickly and reproducibly outside of a laboratory setting, with rapid results and a readout of the resulting test information. Testing can be performed on various bodily fluids, and for certain applications is particularly related to the testing of blood and/or interstitial fluid. Such fluids can be tested for a variety of characteristics of the fluid, or analytes contained in the fluid, in order to identify a medical condition, determine therapeutic responses, assess the progress of treatment, and the like.

The testing of bodily fluids basically involves the steps of obtaining the fluid sample, transferring the sample to a test device, conducting a test on the fluid sample, and displaying the results. These steps are generally performed by a plurality of separate instruments or devices.

One method of acquiring the fluid sample involves inserting a hollow needle or syringe into a vein or artery in order to withdraw a blood sample.

However, such direct vascular blood sampling can have several limitations, including pain, infection, and hematoma and other bleeding complications. In addition, direct vascular blood sampling is not suitable for repeating on a routine basis, can be extremely difficult and is not advised for patients to perform on themselves.

The other common technique for collecting a bodily fluid sample is to form an incision in the skin to bring the fluid to the skin surface. A lancet, knife or other cutting instrument is used to form the incision in the skin. The resulting blood or interstitial fluid specimen is then collected in a small tube or other container, or is placed directly in contact with a test strip. The fingertip is frequently used as the fluid source because it is highly vascularized and therefore produces a good quantity of blood. However, the fingertip also has a large concentration of nerve endings, and lancing the fingertip can therefore be painful. Alternate sampling sites, such as the palm of the hand, forearm, earlobe and the like, may be useful for sampling, and are less painful. However, they also produce lesser amounts of blood. These alternate sites therefore are generally appropriate for use only for test systems requiring relatively small amounts of fluid, or if steps are taken to facilitate the expression of the bodily fluid from the incision site.

Various methods and systems for incising the skin are known in the art. Exemplary lancing devices are shown, for example, in United States Patent Nos. Re 35,803, issued to Lange, et al. on May 19, 1998.; 4,924,879, issued to O'Brien on May 15, 1990; 5,879,311, issued to Duchon et al. on February 16, 1999; 5,857,983, issued to Douglas on January 12, 1999; 6,183,489, issued to Douglas et al. on February 6, 2001; 6,332,871, issued to Douglas et al. on December 25, 2001; and 5,964,718, issued to Duchon et al. on October 12, 1999. A representative commercial lancing device is the Accu-Chek Softclix lancet.

Patients are frequently advised to urge fluid to the incision site, such as by applying pressure to the area surrounding the incision to milk or pump the fluid from the incision. Mechanical devices are also known to facilitate the expression of bodily fluid from an incision. Such devices are shown, for example, in United States Patent Nos. 5,879,311, issued to Duchon et al. on February 16, 1999;

5,857,983, issued to Douglas on January 12, 1999; 6,183,489, issued to Douglas et al. on February 6, 2001; 5,951,492, issued to Douglas et al. on September 14, 1999; 5,951,493, issued to Douglas et al. on September 14, 1999; 5,964,718, issued to Duchon et al. on October 12, 1999; and 6,086,545, issued to Roe et al. on July 11, 2000. A representative commercial product that promotes the expression of bodily fluid from an incision is the Amira AtLast blood glucose system.

The acquisition of the produced bodily fluid, hereafter referred to as the "sampling" of the fluid, can take various forms. Once the fluid specimen comes to the skin surface at the incision, a sampling device is placed into contact with the fluid. Such devices may include, for example, systems in which a tube or test strip is either located adjacent the incision site prior to forming the incision, or is moved to the incision site shortly after the incision has been formed. A sampling tube may acquire the fluid by suction or by capillary action. Such sampling systems may include, for example, the systems shown in US Patent Nos. 6,048,352, issued to Douglas et al. on April 11, 2000; 6,099,484, issued to Douglas et al. on August 8, 2000; and 6,332,871, issued to Douglas et al. on December 25, 2001. Examples of commercial sampling devices include the Roche Compact, Amira AtLast, Glucometer Elite and Therasense FreeStyle test strips.

The bodily fluid sample may be analyzed for a variety of properties or components, as is well known in the art. For example, such analysis may be directed to hematocrit, blood glucose, coagulation, lead, iron, etc. Testing systems include such means as optical (e.g., reflectance, absorption, fluorescence, Raman, etc.), electrochemical, and magnetic means for analyzing the sampled fluid. Examples of such test systems include those in US Patent Nos. 5,824,491, issued to Priest et al. on October 20, 1998; 5,962,215, issued to Douglas et al. on October 5, 1999; and 5,776,719, issued to Douglas et al. on July 7, 1998.

Typically, a test system takes advantage of a reaction between the bodily fluid to be tested and a reagent present in the test system. For example, an optical test strip will generally rely upon a color change, i.e., a change in the wavelength absorbed or reflected by dye formed by the reagent system used. See, e.g., US Patent Nos. 3,802,842; 4,061,468; and 4,490,465.

A common medical test is the measurement of blood glucose level. The glucose level can be determined directly by analysis of the blood, or indirectly by analysis of other fluids such as interstitial fluid. Diabetics are generally instructed to measure their blood glucose level several times a day, depending on the nature and severity of their diabetes. Based upon the observed pattern in the measured glucose levels, the patient and physician determine the appropriate level of insulin to be administered, also taking into account such issues as diet, exercise and other factors.

In testing for the presence of an analyte such as glucose in a bodily fluid, test systems are commonly used which take advantage of an oxidation/reduction reaction which occurs using an oxidase/peroxidase detection chemistry. The test reagent is exposed to a sample of the bodily fluid for a suitable period of time, and there is a color change if the analyte (glucose) is present. Typically, the intensity of this change is proportional to the concentration of analyte in the sample. The color of the reagent is then compared to a known standard which enables one to determine the amount of analyte present in the sample. This determination can be made, for example, by a visual check or by an instrument, such as a reflectance spectrophotometer at a selected wavelength, or a blood glucose meter. Electrochemical and other systems are also well known for testing bodily fluids for properties on constituents.

The present invention provides for enhancing the sampling of a bodily fluid from an incision, particularly by forming the incision in a manner that facilitates the collection of the bodily fluid at the incision site. The invention further includes the use of a passageway positioned proximate to the incising device to collect the bodily fluid sample.

Summary of the Invention

The present invention provides various systems and methods for the sampling of bodily fluid from an incision in the skin. The sampling is achieved using an incising device having a curved, angled or skewed piercing portion. The invention encompasses separate sampling devices as well as combination systems including expression and/or testing systems.

In accordance with one aspect of the present invention, there is provided a sampling device including an incising device coupled with a housing. The incising device includes a piercing portion that extends outwardly of the housing and includes a curved, angled or skewed portion. The housing and/or the incising device defines a sampling passageway having an inlet opening adjacent to, and on the interior side of, the piercing portion. The piercing portion protects the inlet opening from becoming blocked or clogged by the body tissue, and facilitates the collection of the bodily fluid at the incision site.

In another aspect, the present invention provides a test unit that incorporates the sampling device and is operable to incise the skin, collect the bodily fluid from the incision, and analyze a property or constituent of the bodily fluid. The present invention also encompasses methods for incising the skin and collecting the produced bodily fluid by use of a sampling device as described. In further embodiments, the invention includes the combination of the foregoing systems and methods with expressing and/or testing systems and methods, particularly in a single, integrated device.

Brief Description of the Drawings

FIG. 1 is a side, cross-sectional view of a sampling device constructed in accordance with one embodiment of the present invention.

FIG. 2 is a partial front, plan view of the sampling device of FIG. 1, showing the details of the end of the incising device.

FIG. 3 is a side, cross-sectional view of the sampling device of FIG. 1 positioned adjacent to the skin.

FIG. 4 is a partial side, cross-sectional view of the sampling device of FIG. 1 received within and forming an incision in the skin.

FIG. 5 is a front, elevational view of a test device useful in accordance with the present invention.

FIG. 6 is a side, elevational view of the test device of FIG. 5.

FIGS. 7-8 are front and side, cross-sectional views of the test device of FIG. 5, showing in particular the reception of the sampling device therein.

FIG. 9 is a side, cross-sectional view of an alternate embodiment of a sampling device of the present invention.

FIG. 10 is a side, cross-sectional view of another embodiment of a sampling device of the present invention, showing a skewed piercing portion for the incising device.

FIG. 11 is a side, cross-sectional view of an alternate embodiment of a sampling device of the present invention having a skewed piercing portion.

Description of the Preferred Embodiment

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated devices and methods, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

The present invention provides a variety of devices and methods which are useful for the sampling of fluid from an incision in the skin. The invention is useful to form the incision and facilitate the collection of the bodily fluid at the incision site. As used herein, the term "incision" is intended to cover an opening in the skin that permits direct access to the bodily fluid. The term "incising" is intended to mean the forming of the incision in the skin to enable fluid to be accessed directly. The term "incision site" is intended to include the site where an incision either has been or will be formed, unless from the context or express language it is clear otherwise.

The present invention includes an incising device having a piercing portion, defined as the end portion of the incising device which enters the skin in the process of forming the incision in the skin. In accordance with the present invention, the piercing portion is configured to enhance the collection of bodily fluid at the incision site. In one aspect, the piercing portion includes a curved or angled component which enters the skin. In another aspect, the piercing portion is entirely linear but is positioned at an angle to the skin and moved into the skin such that the linear portion does not enter the skin by moving along its lengthwise axis. The latter embodiment is also referred to herein as a "skewed" piercing portion. The result in all instances is that the piercing portion not only pierces into the skin, but also tends to push aside a portion of the tissue as it continues to move below the skin line. This enhances the pooling of the bodily fluid at the incision site by

creating additional space, not occupied by the piercing portion, for the bodily fluid to collect, particularly while the piercing portion remains below the skin line.

The incising device is configured with the housing to provide a sampling passageway on a protected side of the piercing portion. In particular, the incising device includes an exterior side, which is defined as the side of the piercing portion that tends to push the skin away from the incision. For example, for an incising device having a curved piercing portion, the exterior side is on the outside of the curve. The incising device also includes an interior side, which is defined as the side of the piercing portion opposite the exterior side. The sampling passageway includes an inlet opening that is located on the interior side of the piercing portion of the incising device. In this manner, the inlet opening is guarded by the piercing portion as the incising device penetrates into the skin, thereby protecting the inlet opening from becoming blocked or clogged, and enhancing the ability of the bodily fluid to collect at the incision site adjacent to the inlet opening.

The length of the piercing portion will vary with the desired depth of penetration for the incising device. This is in turn related to such factors as the location for fluid sampling, the condition of the skin at that location, and the type of bodily fluid desired for sampling. The depth of penetration therefore generally controls the fluid produced, particularly in combination with the characteristics of the incision site. The present invention is useful with various bodily fluids, including blood or interstitial fluid. The incising device may be configured for production of either blood or interstitial fluid, for example, by controlling the distance which the incising device extends into the user's skin. For example, a depth of 0.25 mm to 4 mm will typically produce blood from the dermis, while a depth of 0.05 mm to 0.5 mm will typically produce interstitial fluid from the epidermis. The length of the piercing portion of the incising device can therefore vary substantially, with preferred lengths for example falling in the range of 0.05 mm to 4 mm, and more preferred lengths being 0.05 mm to 0.5 mm for use with interstitial fluid, and 0.25 mm to 4 mm for use with blood. The piercing portion is accordingly configured to provide a non-orthogonal portion, i.e., a curved, angled or skewed component, within this distance from the tip of the incising device.

Referring to the drawings, a first embodiment of the present invention is shown in FIGS.1-2 in which there is provided a sampling device 10 for use in the sampling of a bodily fluid from an incision in the skin. The sampling device includes a housing 12 and an incising device 14 coupled with the housing. The incising device 14 comprises a lancet 16 including a piercing portion 18 extending outwardly from the housing. The piercing portion includes a piercing end 20 and is curved along its length. The piercing portion includes an interior side 22 on the inside of the curve, and an opposite, exterior side 24. The incising device further comprises a cylindrical body 26 defining a passageway 28 having an inlet opening 30 positioned adjacent to the piercing end 20 on the interior side 22 of the incising device. As previously described, the piercing portion may instead be formed with an angle, a combination of curves and/or angles, or other configurations providing a non-linear, non-orthogal component as it enters the skin to form the incision.

The sampling device 10 further includes a test strip holder 32 defining an interior chamber 34 in fluid communication with the passageway 28. The test strip holder includes an open end 36 in which a test strip 38 (FIG. 3) may be inserted. The holder also includes a transparent window 40, or alternatively an opening, which is aligned with the passageway 28 and allows a meter 42 to read the test strip upon use.

The sampling device 10 is used as follows. The housing 12 and lancet 16 are positioned above the skin 44 at the position shown in FIG. 3. The housing and lancet are then advanced down toward the skin to form an incision 46 in the skin to the desired depth. The piercing portion is shown in FIG. 4 as comprising the full length of the incising device which extends outside of the housing, but the piercing portion could instead comprise only a portion of this length. This piercing portion is advanced toward the skin along a direction 48 (FIG. 3).

As shown in FIG. 4, the curve of the lancet 16 tends to push the skin at the exterior side 24 of the curve away from the incision, creating a gap in which bodily fluid 50 is allowed to collect on the interior side. The lancet is maintained in this position within the skin for a brief time, with the lancet being withdrawn almost immediately or within a very short time, in the order of ____ to ____ seconds.

Maintaining the lancet within the incision will facilitate the collection of the bodily fluid. However, the lancet will typically be removed relatively quickly to avoid causing undue pain to the user.

The lancet and housing are moved in the direction away from the skin a sufficient distance for collecting the bodily fluid within the sampling passageway 28. In one aspect, the lancet is removed entirely from the incision to a location such as shown in FIG. 3. As the bodily fluid forms a droplet at the incision site, it will contact the inlet opening 30 and will be drawn into the sampling passageway 28, such as by capillary action or by vacuum. Alternatively, the lancet may be partially withdrawn from the incision to a position intermediate those shown in FIGS. 3 and 4. For example, the incising device may be positioned with the inlet opening located above, at or below the skin line. In each instance, the bodily fluid is allowed to collect at the incision site and is then drawn into the sampling passageway. It is apparent that the use of the curved piercing portion facilitates the collection of the bodily fluid, and also protects the inlet opening from becoming blocked or clogged by body tissue.

The bodily fluid is thereby collected and is available for further use or analysis. In one aspect of the present invention, the sampling device operates solely as an implement for creating and collecting a sample of bodily fluid. In another aspect, the sampling device is operable to test properties or constituents of the bodily fluid sample. For example, as shown in the drawings, the bodily fluid received within the passageway 28 moves by capillary or other action to a test strip 38 positioned within the holder 32. The bodily fluid contacts the underside of the test strip and thereby wets a suitable test area located in alignment with the window 40. This test area may comprise a chemical reagent which is read by optical means, an electrochemical test system, or other testing systems of the types well known in the art. As depicted, the test strip may include a reagent that reacts with the bodily fluid and produces a color or other change that is read by the meter 42. The sampling device is therefore understood to readily provide a system for creating, collecting and analyzing a bodily fluid sample, separately or all within a single, integrated unit.

It is a feature of the present invention that the sampling device is useful as an integral unit that is disposable after each use. This allows for a new incising device and sampling passageway to be available for each new use. In this regard, the test system may also be provided to be disposable with the sampling device. This initial embodiment of the sampling device is shown as using a separate test strip received within a holder. However, it will be appreciated that the sampling device may instead include an integral test area, such as chemical reagents deposited directly on a surface of the sampling device. In either approach, the test system is also disposable with the sampling system, and may be provided in the manner of a cartridge that is readily replaced in a supporting test unit.

Referring now to FIGS. 5-8, there is shown in somewhat diagrammatic form a test unit useful in combination with the sampling system of FIGS. 1-4. The test unit 60 includes a body 62, a display 64, at least one button 66 to operate the unit, a calibration interface 68, and the sampling system 10 (FIG. 7). The calibration interface 68 is adapted to receive a device which contains information for the calibration of the test unit 60. For example, the calibration interface 68 may be adapted to receive a microchip wherein the microchip is calibrated for a given number of uses and/or contains constants needed to perform tests with the test unit.

The test unit 60 includes conventional means for advancing and retracting the sampling device. For example, the test unit may include a nose cone 70, and a carriage 72 which is translatable relative thereto. The test unit also includes driving and return springs (not shown), which function in conventional fashion to move the carriage and the supported sampling device between a first, extended position for creating an incision in a person's skin and a second, retracted position for receiving bodily fluid collecting at the incision. The function and configuration of such springs and associated mechanisms are well known in the art and therefore are not further described herein. An optics housing 74 is coupled to the carriage 72 and includes an optical testing system which includes a light source, such as an LED, and a device for receiving light reflected from the test area of the test strip.

Test units of the general type described are well known in the art. The Odyssey One-Step System of Amira is a commercial example of such a test unit.

Test strips of the type described herein are also well known in the art, and include strips such as described in US Patent Nos. 5,968,765, issued to Grage et al. on October 19, 1999; 5,876,957, issued to Douglas et al. on March 2, 1999; and 6,121,011, issued to Douglas et al. on September 19, 2000. The foregoing patent disclosures are hereby incorporated by reference. However, it will be appreciated that the sampling systems of the present invention are useful with a wide variety of such test units and systems, and therefore is not limited to any particular unit or system.

In using the test unit 60, a test strip 38 is inserted into the holder 32 and the unit is positioned for lancing the desired area of skin, such as the fingertip or forearm. The sampling system 10 comprising the housing 12 and incising device 14 are initially in a retracted position with the lancet inside of the test unit 60. The driving spring is activated to move the lancet quickly into the skin to form an incision. The return spring thereafter withdraws the lancet to the desired sampling position, either within or closely above the skin surface. The bodily fluid is thereby received within the sampling passageway and moves to the test area for analysis. The test unit is further operable to display the test results to the user.

In another aspect, the sampling device 10 includes a distal end surface 76 which is adapted to be received against the surface portion 78 of the nose cone 70. This represents the extended position of the sampling device for creation of the incision, and the surface portion 78 operates as a hard stop for the forward travel of the sampling device. By providing a hard stop this reduces the pain associated with the procedure because the patient" skin is not being utilized to stop the forward motion of the needle. Additionally, a driving spring having a greater force constant which will drive the spring into the patient's skin at a higher rate of speed may be utilized because the hard stop will control the forward motion of the sampling device.

Referring to FIG. 9, there is shown an alternative embodiment of sampling device of the present invention. Sampling device 80 includes a housing 82 and an incising device 84. However, in comparison to the prior embodiment, the sampling device 80 also includes a tube 86 defining the sampling passageway 88

having an inlet opening 90 on the interior side 92 of the incising device. The sampling device 80 is otherwise configured and functions in the manner as described with respect to the embodiment of FIG. 1

In another embodiment of the invention, the sampling device includes a skewed incising device. As shown in FIG. 10, the provision of a skewed incising device may be accomplished in one approach by moving a linear piercing portion toward the skin at an angle to the longitudinal axis of the piercing portion. Sampling device 100 is similar to the embodiment of FIG. 9, except that the incising device 102 includes a linear piercing portion 104. Further, the sampling device is positioned at an angle to the skin surface 106 and is moved toward the skin along the direction 108, which is orthogonal to the skin surface and is angled or skewed in relation to the longitudinal axis 110 of the piercing portion 104. It is apparent from FIG. 10 that this direction of movement will provide a similar function to that obtained with the non-linear piercing portion of FIG. 1 in that the exterior side 112 will encounter and push aside the skin tissue as the piercing portion forms the incision. Further, the inlet opening 114 of the sampling passageway 116 is protected by being positioned on the interior side 118 of the piercing portion. This embodiment in FIG. 10 demonstrates that the present invention further contemplates the use of a more standard type of lancing or other incising implement, but which is skewed as it is applied toward the skin to make the incision.

A second version of the skewed piercing portion is shown in FIG. 11, in which the sampling device 130 includes a housing 132 and an incising device 134 including a piercing portion 136 which is linear. However, the linear piercing portion 136 extends outwardly from the housing 132 at an angle to the housing centerline 138 and the axis of travel 140 for the housing relative to the skin surface 142. The sampling device further includes a tube 144 a sampling passageway 146 with an inlet opening 148. In this embodiment, the incising device and tube are shown as being fully linear and extending at an angle within the housing 132. It will be appreciated, however, that the incising device and/or the tube need not be fully linear, and may therefore be oriented differently within the housing.

The sampling device 130 is used by pressing the piercing portion 136 against the skin 142 along the direction of travel 140, which is different than the longitudinal axis of the piercing portion. The result is the same as for the prior embodiment with the piercing portion protecting the inlet opening from the skin tissue, and facilitating the collection of bodily fluid at the incision site.

The sampling passageway may be formed in the foregoing embodiments either as a part of a hollow needle or other incising device, or separately therefrom. For example, the foregoing embodiments of FIGS. 10 and 11 are shown with a separate incising device and capillary tube defining the sampling passageway. Alternatively, the housing may define the sampling passageway without the use of a capillary tube, such as by a passageway formed directly in the housing. Further, the incising device may instead comprise a hollow element which includes a piercing end and which defines a sampling passageway, as shown for example in the embodiment of FIG. 1.

It will be appreciated from the foregoing descriptions that the several forms of sampling systems comprising the present invention are useful independently of the presence or type of expressing and/or testing systems. In certain embodiments, however, the sampling mechanisms and methods are combined with expressing and/or testing systems. It will be appreciated by those skilled in the art that the function of the sampling system is achieved independent of these other systems, and therefore is useful with a variety of such systems as are known in the art. However, the sampling systems are advantageously combined with such other systems in a single, integrated device, and are useful in combination with a wide range of incising, expressing and testing systems, including those herein described in the patents identified in the description of the prior art and elsewhere, and the disclosures of such patents are hereby incorporated by reference.

As shown in the drawings, such an integrated device preferably operates such that the device does not have to be repositioned at any time during the process of incising, expressing, and/or sampling. More specifically, the device preferably carries incising, expressing, sampling and testing systems to perform a complete, integrated monitoring of the bodily fluid. In accordance with this approach, the

device is moved against the skin and is maintained in this position while the incision is formed, and also while the resulting fluid droplet develops and is carried into the sampling device. The fluid is then analyzed by the test system and the result of the analysis is provided to the user. All of these actions therefore may be accomplished by a single, integrated unit, providing a simple, quick and reliable method for acquiring and testing a bodily fluid.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A sampling device for use in the sampling of a bodily fluid from an incision in the skin, comprising:

a housing; and

an incising device coupled with said housing, said incising device including a piercing portion having a piercing end, the piercing portion having an interior side and an exterior side, the exterior side being configured to include a portion which is non-orthogonal relative to the skin during insertion of the piercing portion into the skin, at least one of said housing and said incising device defining a sampling passageway having an inlet opening on the interior side of the piercing portion adjacent to the piercing end.

2. The sampling device of claim 1 in which the sampling passageway is a capillary passageway.

3. The sampling device of claim 1 and which further includes a test system connected with said incising device in fluid communication with the sampling passageway.

4. The sampling device of claim 3 in which said test system comprises a test strip.

5. The sampling device of claim 3 in which said test system is coupled with said housing in a single, disposable unit.

6. The sampling device of claim 1 in which said incising device comprises a curved, hollow needle defining the sampling passageway.

7. The sampling device of claim 1 in which said incising device comprises an angled, hollow needle defining the sampling passageway.

8. The sampling device of claim 1 in which said housing defines the sampling passageway separate from said incising device.

9. The sampling device of claim 8 in which said housing includes a capillary tube mounted within said housing and defining the sampling passageway.

10. A sampling system for use in the sampling of a bodily fluid from an incision in the skin, comprising:

a system housing; and

a sampling device including a cartridge housing and an incising device coupled with the cartridge housing, the incising device including a piercing portion having a piercing end, the piercing portion having an interior side and an exterior side, the exterior side being configured to include a portion which is non-orthogonal relative to the skin during insertion of the piercing portion into the skin, at least one of the cartridge housing and the incising device defining a sampling passageway having an inlet opening on the interior side of the piercing portion adjacent to the piercing end; said sampling device being mounted to said system housing and having a first, extended position for creating an incision in a person's skin, and a second, retracted position for receiving bodily fluid collecting at the incision.

11. The sampling system of claim 10 and which further comprises a means for moving said sampling device between the first and second positions.

12. The sampling system of claim 10 in which the sampling passageway is a capillary passageway.

13. The sampling system of claim 10 and which further includes a test system connected with the incising device in fluid communication with the sampling passageway.

14. The sampling device of claim 13 in which said test system comprises a test strip.

15. The sampling device of claim 13 in which said test system is coupled with said cartridge housing in a single, disposable unit.

16. The sampling device of claim 10 in which the incising device comprises a curved, hollow needle defining the sampling passageway.

17. The sampling device of claim 10 in which the incising device comprises an angled, hollow needle defining the sampling passageway.

18. The sampling device of claim 10 in which said cartridge housing defines the sampling passageway separate from the incising device.

19. The sampling device of claim 18 in which said cartridge housing includes a capillary tube mounted within said cartridge housing and defining the sampling passageway.

20. A method for sampling a bodily fluid from an incision in the skin comprising:

providing a sampling device including a housing and an incising device coupled with the housing, the incising device including a piercing portion having a piercing end, the piercing portion having an interior side and an exterior side, the exterior side being configured to include a portion which is non-orthogonal relative to the skin during insertion of the piercing portion into the skin, at least one of the housing and the incising device defining a sampling passageway having an inlet opening on the interior side of the piercing portion adjacent to the piercing end;

advancing the sampling device against the skin to pierce the skin with the piercing portion of the incising device; and

maintaining the incising device adjacent to the skin to collect bodily fluid from the incision through the inlet opening and into the sampling passageway.

21. The method of claim 20 and which further includes applying a vacuum to the sampling passageway to draw the bodily fluid in through the inlet opening.

22. The method of claim 20 in which the sampling passageway comprises a capillary passageway and the bodily fluid is drawn in through the inlet opening and into the sampling passageway by capillary action.

23. The method of claim 20 and which further includes testing the collected bodily fluid.

24. The method of claim 20 in which the piercing portion is curved.

25. The method of claim 20 in which the piercing portion is straight and said advancing comprises advancing the piercing portion into the skin at a non-orthogonal angle relative to the skin.

26. The method of claim 20 in which the incising device is a hollow needle.

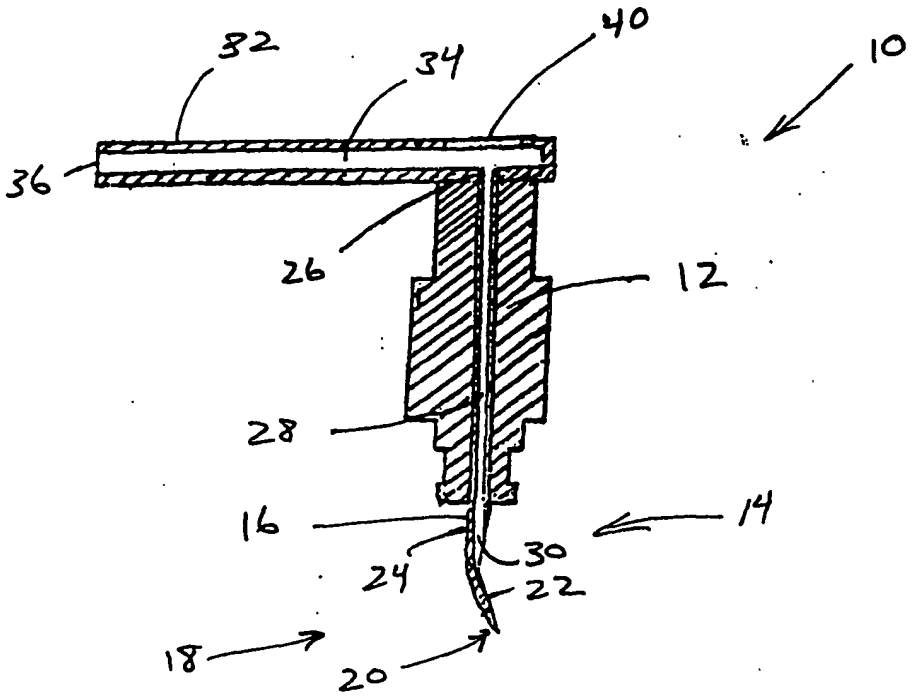

FIG. 1

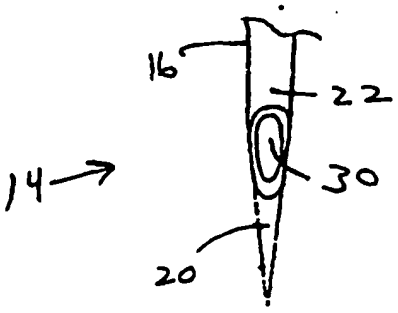

FIG. 2

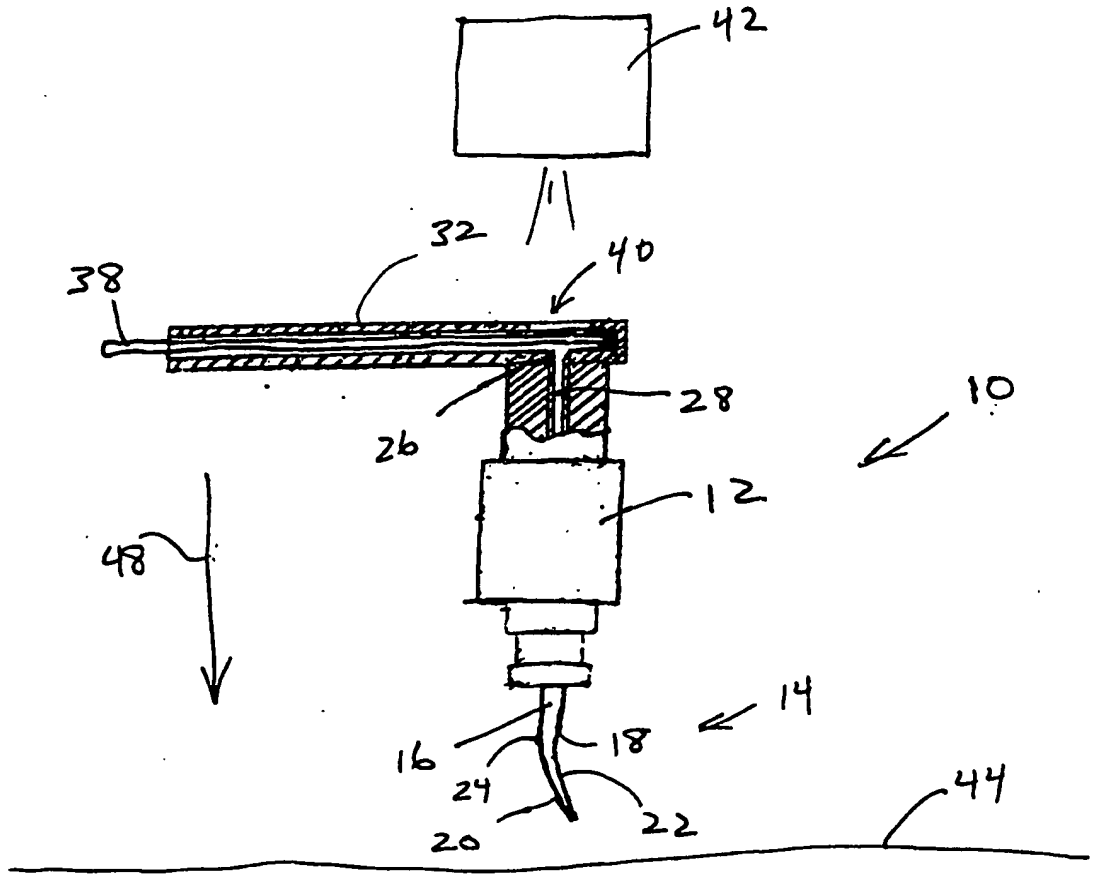

FIG. 3

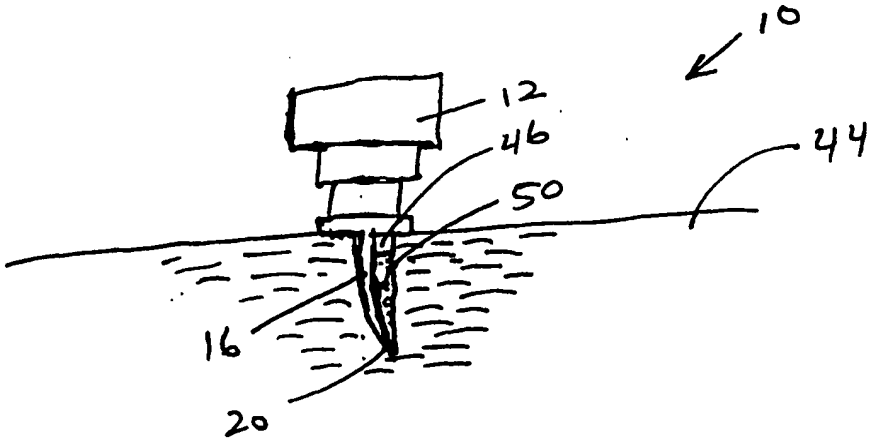

FIG. 4

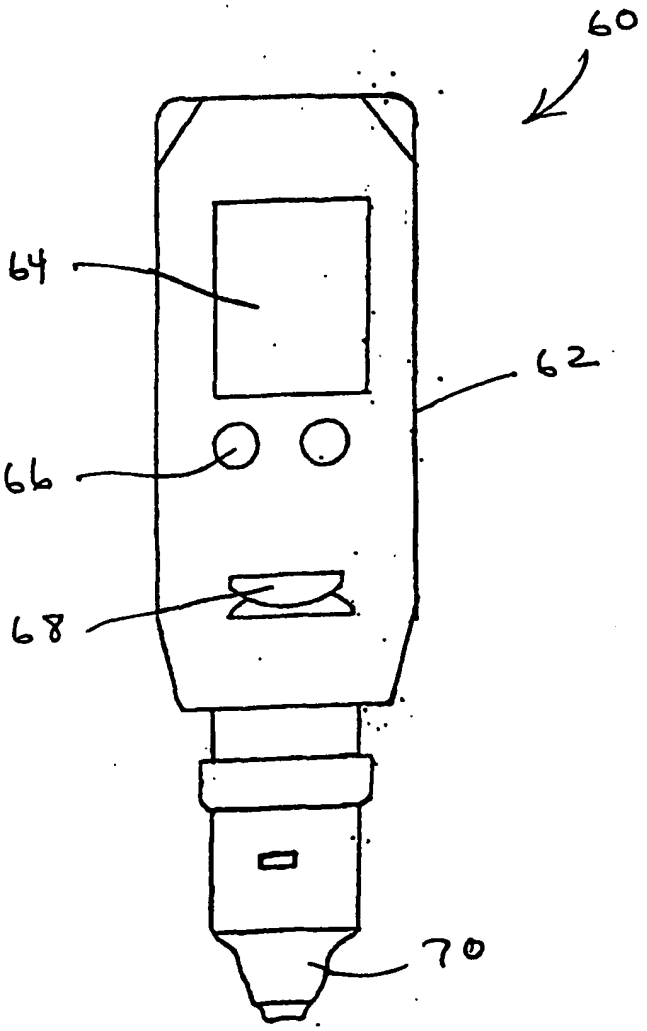

FIG. 5

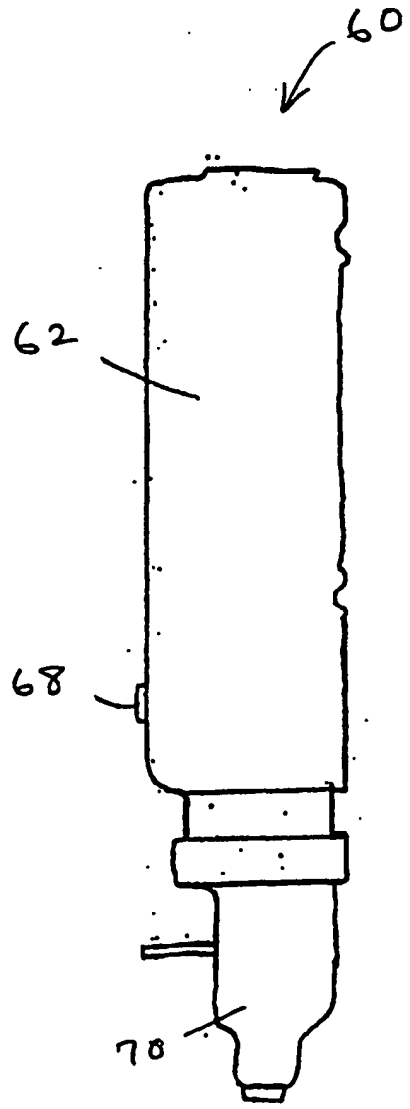

FIG. 6

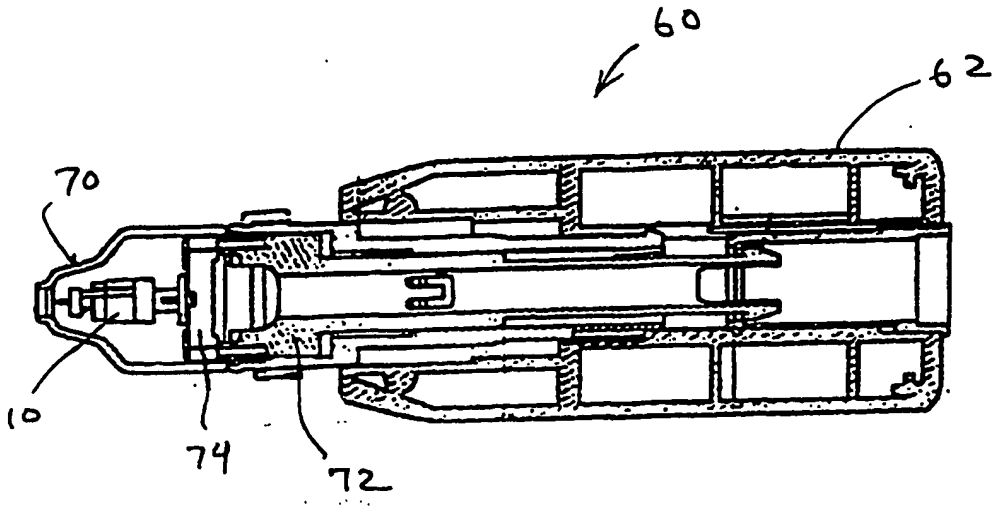

FIG. 7

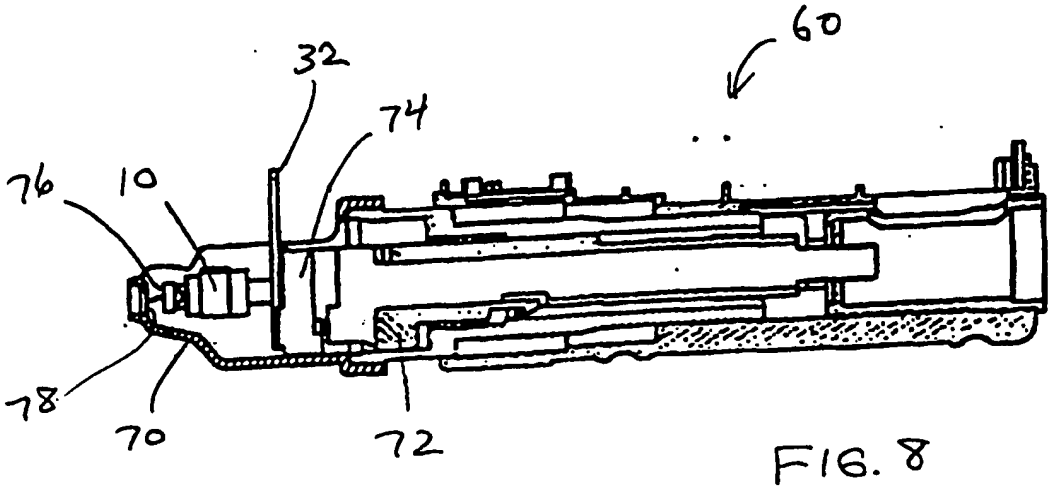

FIG. 8

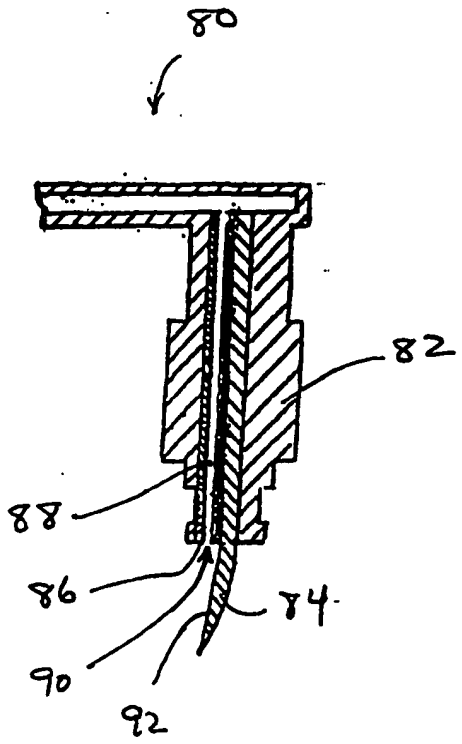

FIG. 9

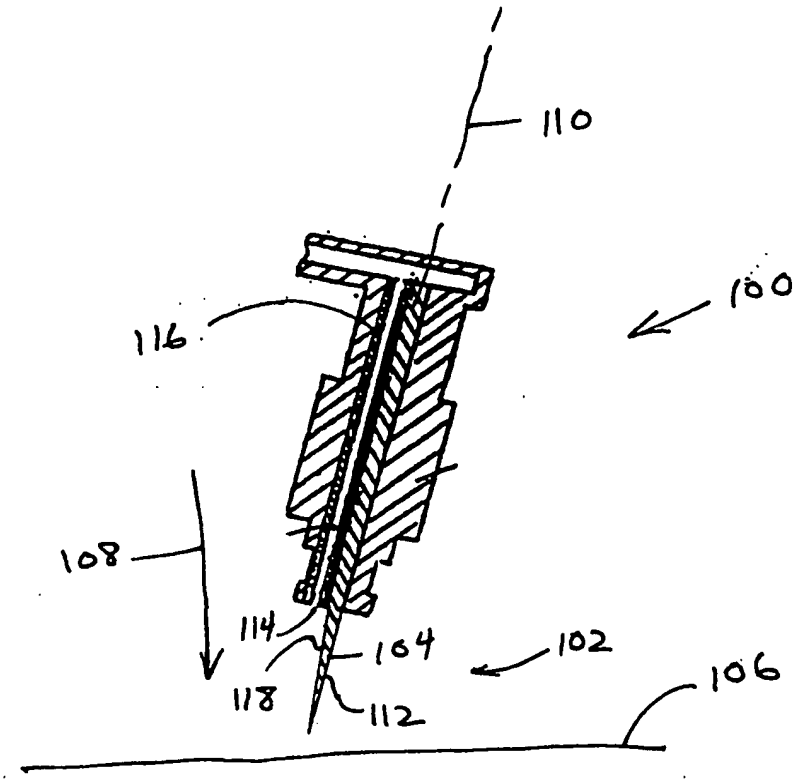

FIG. 10

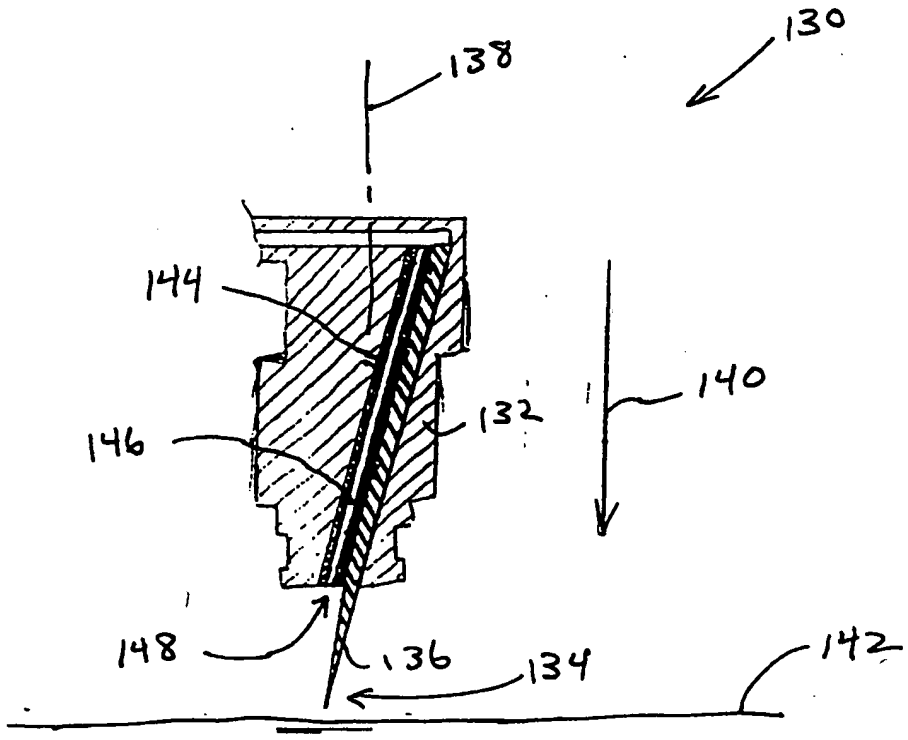

FIG. 11

INTERNATIONAL SEARCH REPORT

National Application No
PCT/US 02/18160

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/15 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 45708 A (INTEG INC) 10 August 2000 (2000-08-10) page 3, line 8 -page 5, line 21; figures 1-5	1-3,6,7, 10-13, 16,17
Y		4,5,8,9, 14,15, 18,19

Y	US 4 627 445 A (GARCIA FERNANDO S ET AL) 9 December 1986 (1986-12-09) abstract column 6, line 1-65; figure 4 column 10, line 57-68; figure 9	4,5,8,9, 14,15, 18,19

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

'A' document defining the general state of the art which is not considered to be of particular relevance

'E' earlier document but published on or after the international filing date

'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

'O' document referring to an oral disclosure, use, exhibition or other means

'P' document published prior to the international filing date but later than the priority date claimed

'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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'&' document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 August 2002	04/09/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Dhervé, G

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/18160

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 823 973 A (RACCHINI JOEL R ET AL) 20 October 1998 (1998-10-20) the whole document	1-3, 10-13
X	US 5 193 552 A (PALMER HARVEY J ET AL) 16 March 1993 (1993-03-16) abstract column 6, line 18-22; figures 10,14	1,2, 10-12
X	US 4 383 530 A (BRUNO JOHN) 17 May 1983 (1983-05-17) column 4, line 67 -column 5, line 63; figures 2-4	1,2,6,7
X	US 4 368 738 A (TERSTEEGEN BERND ET AL) 18 January 1983 (1983-01-18) column 5, line 30 -column 6, line 30; figure 1	1,2,7
X	US 5 456 875 A (LAMBERT JAMES M) 10 October 1995 (1995-10-10) column 3, line 20-37; figures	1,2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/18160

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 20-26
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

national Application No
PCT/US 02/18160

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Information on patent family members

International Application No
PCT/US 02/18160

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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